

FEB 15 2006

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K051295

1. Submitter's Identification:

Westridge Laboratories, Inc.  
1671 Saint Andrew Place  
Santa Ana, CA 92705  
Telephone: (714) 259-9400  
Fax: (714) 259-9401

Contact Person: Gregg Haskell, President

Date of Summary: May 12, 2005

2. Device Name: I-D Glide

3. Classification Name: Lubricant

4. Substantial Equivalence Statement: This product is similar in design, intended use and function to many other lubricants on the market. Section 5 contains a comparison of I-D Glide Personal Lubricant with Instead, Inc.'s Instead Intimate Lubricant and Qualis, Inc.'s Personal Lubricating Gel.

<i>Company</i>	<i>Product</i>	<i>510(k) #</i>
Instead, Inc.	Instead Intimate Lubricant	K033776
Qualis, Inc.	Personal Lubricating Gel	K041129

5. Intended Use: I-D Glide lubricant is intended enhance the comfort and ease of intimate activity and is compatible with latex and polyurethane condoms.

6. Device Description: I-D Glide Personal lubricant is a water-based non-sterile personal lubricant containing purified water, glycerin, propylene glycol, cellulose polymer, PEG 90m, Carbomer 981, various antifungal preservatives, pH adjuster, and chelating agent.

7. Predicate Product Comparison:

	<b>Westridge Laboratories, Inc. I-D Glide</b>	<b>Instead, Inc Instead Intimate Lubricant</b>	<b>Qualis, Inc. Personal Lubricating Gel</b>
<b>Common Name</b>	<b>Lubricant</b>	<b>Lubricant</b>	<b>Lubricant</b>
<b>Product Code</b>	<b>80 MMS</b>	<b>80 MMS</b>	<b>80 MMS</b>
<b>Intended Use</b>	<b>Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.</b>	<b>Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.</b>	<b>Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.</b>
<b>Over the Counter Use</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Water-soluble</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Contains purified water</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Contains Preservatives</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Biocompatibility Tested</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Antimicrobial Tested</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>Sterile</b>	<b>NO</b>	<b>NO</b>	<b>NO</b>

Product comparison chart shows that the Westridge Laboratories, Inc.'s I-D Glide is equivalent to the Predicate Products (Instead Inc. Instead Intimate Lubricant and Qualis Inc, Personal Lubricating Gel) in intended use and design. Westridge Laboratories, Inc. believes that the I-D Glide presents no new concerns of safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 15 2006

Westridge Laboratories, Inc.  
% Albert Rego, Ph.D.  
Scientific Consultant  
27001 La Paz Road, Suite 314  
MISSION VIEJO CA 92691

Re: K051295  
Trade/Device Name: I-D Glide Lubricant  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: January 20, 2006  
Received: January 20, 2006

Dear Dr. Rego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051295

Device Name: I-D Glide Lubricant

Indications For Use: Personal lubricant for penile and vaginal use only. Compatible with latex and polyurethane condoms.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number   K051295  

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